

(12) UK Patent Application (19) GB (11) 2 397 528 (13) A

(43) Date of A Publication 28.07.2004

(21) Application No: 0301740.7

(22) Date of Filing: 24.01.2003

(71) Applicant(s):
Enfis Limited
(Incorporated in the United Kingdom)
Technium, Kings Road, The Docks,
SWANSEA, SA1 8PH, United Kingdom

(72) Inventor(s):
Gareth Jones
Kenneth Board
Gareth Peter Evans

(74) Agent and/or Address for Service:
Abel & Imray
20 Red Lion Street, LONDON, WC1R 4PQ,
United Kingdom

(51) INT CL⁷:
A61N 5/06

(52) UK CL (Edition W):
A5R REHR

(56) Documents Cited:
GB 2368020 A EP 0726083 A2
US 20020161418 A

(58) Field of Search:
UK CL (Edition V) A5R REHR
INT CL⁷ A61N 5/06
Other: Online: EPODOC, JAPIO, WPI

(54) Abstract Title: Apparatus and method for treatment of skin conditions

(57) A method and apparatus for improving the cosmetic appearance of a region of skin 11 affected by Acne Vulgaris, Rosacea or similar skin condition by means of directing light radiation 12 from an illuminating device 1 on to the skin 11. The apparatus 10 comprises a control unit 9 that operates one or more LEDs 7 (light emitting diodes) of the illuminating device 1. Each dose of light radiation 12 lasts for at least 100ms, during which time the skin 11 receives light energy from the LED(s) 7, which causes a photochemical reaction that stimulates the production of free radicals (singlet oxygen) that react with, and at least partially disable or destroy, bacteria that contribute to the symptoms of the skin condition. The light energy directed on to the skin 11 during any given period of 10 μ s is less than 0.5 Jcm⁻², and during any given period of 100ms is less than 5 Jcm⁻². Substantially no beneficial photo-thermal reaction occurs within the skin 11. Light having wavelengths around 405nm and/or 585nm is used. The duration of a single dose may be much longer than 100ms and can last up to 10 hours (for overnight treatment).

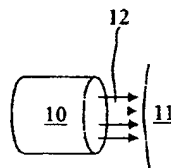


Fig 1

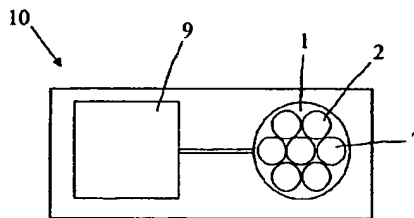


Fig 2

GB 2 397 528 A

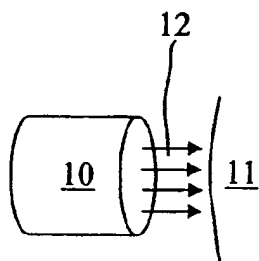


Fig 1

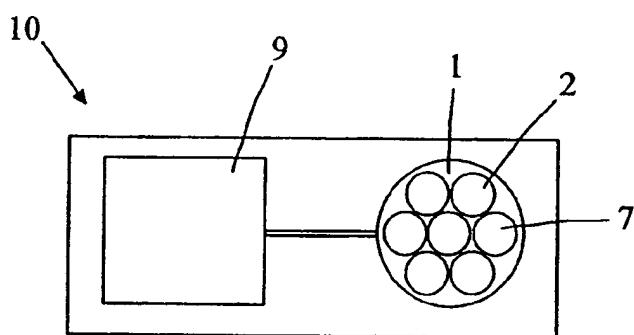


Fig 2

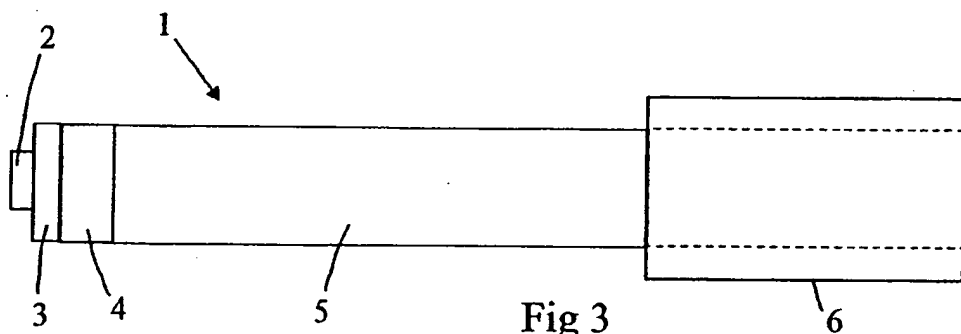


Fig 3

Apparatus and method for treatment of skin conditions

The present invention relates to an apparatus and method for
5 the cosmetic treatment of a skin condition. In particular, the
invention relates to an apparatus and a non-surgical method for
the cosmetic treatment of Acne Vulgaris.

Acne Vulgaris is a skin condition which affects almost 100%
of the population at some point in their lives. It is a
10 condition of the sebaceous follicles (pores) and can lead to
lesions on the skin, primarily on the face, shoulders and back.
The symptoms of Acne Vulgaris, and of other similar skin
conditions, can be unsightly and undesirable cosmetically.

Acne Vulgaris is caused by a number of factors, of which the
15 most significant are believed to be: excessive hormone production
(especially androgens), excessive sebum production (sebum is an
oily substance produced by the sebaceous glands to keep the skin
soft, pliable and waterproof), excessive dead cell shedding, the
presence of bacteria (particularly *Propionibacterium acnes*) in
20 the sebaceous follicles and the bodies inflammatory response
(chemotaxis).

The process starts when dead skin cells and the oily
substance sebum combine to block the skin's sebaceous follicles.
The dead skin and sebum form a plug which traps oil and bacteria
25 within the sebaceous follicles. The sebaceous follicle begins to
swell as the as the skin continues its normal oil production.
Normal skin bacteria *Propionibacterium acnes* multiply rapidly in
the clogged pore. The multiplication of the bacteria produces
substances which cause inflammation in the follicle and
30 surrounding skin. The body's response is to send white blood
cells to the inflamed areas.

The lesions range in severity and can be defined as
comedones, papules, nodules, pustules and cysts. Comedones are

sebaceous follicles that have become blocked. Papules are small (less than 5mm) solid lesions slightly above the surface of the skin. Nodules are larger papules (greater than 5mm). Pustules are dome shaped fragile lesions typically containing a mixture of white blood cells, dead cells and bacteria. Cysts are similar to pustules but are larger and are severely inflamed and often lead to scarring.

Various drug treatments are known to be at least partially effective in preventing Acne Vulgaris.

10 A treatment for Acne Vulgaris using light radiation is disclosed in GB 2 368 020. In the embodiments disclosed, radiation is provided at specific energy densities and wavelengths in order to cause photo-chemical and photo-thermal reactions in the skin. The photo-chemical reaction leads to a partial disabling or eradication of a cause of the skin condition while the photo-thermal reaction increases collagen production, thereby helping to reduce the risk of scarring.

The method disclosed in GB 2 368 020 requires the provision of relatively high doses of radiation (0.5Jcm^{-2} to 5Jcm^{-2}) in short periods of time (10ps to 100ms) in order to produce the photo-thermal effects in the skin. Providing these high energy levels over short periods of time requires high power lasers. These are expensive to manufacture and operators may be required to have specialist training and knowledge to use them safely and effectively.

25 It is an object of the invention to provide an apparatus for improving the appearance of the skin, for example an apparatus for the treatment of a skin condition, that is relatively inexpensive and/or simple to operate. It is an alternative or additional object of the invention to provide a method for improving the appearance of the skin or for the cosmetic

treatment of a skin condition that is relatively inexpensive and/or simple to carry out.

According to one aspect of the invention there is provided an apparatus for the treatment of a skin condition comprising

5 an illuminating device, and

a control unit for controlling the operation of the illuminating device, wherein

the illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by the skin condition, which reaction would result in agents causing the skin condition being at least partially disabled or destroyed, and

15 the control unit and illuminating device are so arranged and configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:

the light energy received at said area during a period of at least 100ms is at least 0.01 Jcm^{-2} ,

the light energy received at said area in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and

the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} , whereby

25 the apparatus may be used to treat the skin condition.

According to another aspect of the invention there is provided an apparatus for improving the cosmetic appearance of the skin of a mammal, the apparatus comprising

an illuminating device for emitting light radiation, and

30 a control unit for controlling the operation of the illuminating device, wherein

the control unit is so arranged and configured that it is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:

5 the light energy received at said area during a period of at least 100ms is at least 0.01 Jcm^{-2} ,

the light energy received at said area in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and

10 the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} , whereby

the apparatus may be used to improve the cosmetic appearance of the skin. The illuminating device may be so arranged and configured that it is able, when being used to direct light onto the skin, to emit light radiation of an energy and wavelength
15 profile sufficient to cause a photochemical reaction within an area of the skin being targeted. The photochemical reaction may be caused in such a way that it partially disables or destroys agents in the skin that are causing the cosmetic appearance of the skin to be worsened.

20 Further optional or preferred features of the apparatus according to either of the above-mentioned aspects of the invention are described below.

The illuminating device preferably comprises one or more light emitting semiconductor devices. The or each semiconductor
25 device may be in the form of a diode. The illuminating device may for example comprise one or more LEDs. LEDs are, advantageously relatively inexpensive and simple to operate in comparison to lasers. Laser diodes may additionally or alternatively be used. Conveniently, the illuminating device is
30 in the form of a device, for example comprising at least one semiconductor device that in use acts as the active light

emitting element(s), that has a power input requirement of less than 500W, and preferably less than 100W, per individual semiconductor device.

5 The control unit and illuminating device of the apparatus may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver light energy of between 0.01 and 100 Jcm⁻² to said area during a period of between 200ms and 3 seconds, or more preferably during a period of between 300ms and 2 seconds. Of course, the control unit and
10 illuminating device may be arranged to emit radiation during a single treatment over a longer period of time, so that during a single treatment more than 100 Jcm⁻² is delivered over a period of greater than 3 seconds. A single treatment might last as long as up to 10 hours. Such a treatment might for example be
15 provided overnight. Preferably, the control unit and illuminating device of the apparatus are so configured and arranged that less than 100 Jcm⁻² of light energy is delivered during any period of 3 seconds.

The control unit and illuminating device may be so
20 configured and arranged that the illuminating device delivers pulsed light radiation during a single treatment. Alternatively, the control unit and illuminating device may be so configured and arranged that the illuminating device delivers continuous light radiation during a single treatment. The apparatus may be so
25 configured to be able to deliver either continuous or pulsed radiation at the choice of the user.

The control unit and illuminating device of the apparatus may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver light energy
30 of between 0.5 Jcm⁻² and 3 Jcm⁻² to said area during a period of between 100ms and 100 seconds. The control unit and illuminating device may be so configured and arranged that the control unit is

able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10 seconds (or more preferably between 200ms and 3 seconds) and the energy of the light radiation delivered during the single dose being greater than 0.1 Jcm^{-2} and being equal to $T_1 \times P_1$, where T_1 = the length in time of the single dose and P_1 has the units of optical power density (power per unit area) and satisfies $0.2 \text{ Wcm}^{-2} < P_1 < 20 \text{ Wcm}^{-2}$.

The apparatus may be in the form of a top up apparatus allowing lower levels of light energy to be delivered. For example, the control unit and illuminating device may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 300ms and 10 seconds (or more preferably between 300ms and 3 seconds) and the energy of the light radiation delivered during the single dose being equal to $T_2 \times P_2$, where T_2 = the length in time of the single dose and P_2 has the units of optical power density (power per unit area) and satisfies $0.01 \text{ Wcm}^{-2} < P_2 < 1 \text{ Wcm}^{-2}$. P_2 may satisfy the condition $0.1 \text{ Wcm}^{-2} < P_2 < 0.5 \text{ Wcm}^{-2}$.

The apparatus may be so configured and arranged that it is suitable for treatment of relatively small areas at a time. For example, the apparatus may be so configured and arranged that, during a single dose of light radiation, an area of skin of between 12 and 200 mm^2 is treated.

The apparatus may be so configured and arranged that it is suitable for lower power operation over longer periods of time. For example, the control unit and illuminating device may be so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10

hours (more preferably between 10 seconds and 8 hours), light radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than 0.1 Jcm^{-2} and being equal to $T_3 \times P_3$, where T_3 = the length in time of the single treatment and P_3 has the units of optical power density (power per unit area) and satisfies $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$. The longer treatment may last for at least 30 seconds, preferably lasts for at least 10 minutes and more preferably lasts for at least an hour.

The apparatus may be so configured and arranged that it is suitable for treatment of relatively large areas at a time. For example, the apparatus may be so configured and arranged that, during a single treatment, an area of skin of between 0.003 m^2 and 0.5 m^2 is treated. Such an apparatus is preferably arranged such that the energy of the light radiation delivered during a single treatment is equal to $T_3 \times P_3$, where T_3 = the length in time of the single treatment and P_3 has the units of optical power density (power per unit area) and satisfies $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$.

The illuminating device is preferably arranged to provide light radiation including radiation having a wavelength of between 350nm and 1500nm. The illuminating device is preferably arranged to emit radiation at a wavelength between 350nm and 1000nm, more preferably between 350nm and 700nm. The illuminating device is preferably arranged to provide light radiation including radiation having a wavelength between 570nm and 600nm. The illuminating device may alternatively or additionally be arranged to provide light radiation of a wavelength between 390nm and 420nm, and preferably includes light radiation having a wavelength of about 405nm.

The photo-chemical reaction that may be caused by the apparatus when used to treat the skin may take place in Porphyrin,

which is a naturally occurring substance produced by the bacteria *Propionibacterium acnes*. Further discussion is provided below in relation to a method according to another aspect of the invention. The Porphyrin activation spectrum has peaks at both about 585nm
5 and 405nm. Providing light radiation including light having a wavelength between 390nm and 420nm and including light having a wavelength between 570nm and 600nm is considered to be particularly advantageous as such a combination may activate Porphyrin at different depths in the skin tissue.

10 Also, it is believed that red light (of a wavelength between 630nm and 680nm) may aid in the wound healing process.

The illuminating device is preferably arranged to provide light radiation having a peak power level of less than 100Wcm^{-2} . More preferably, the illuminating device is preferably arranged
15 to provide light radiation having a peak power level of less than 10Wcm^{-2} . Even more preferably, the illuminating device is preferably arranged to provide light radiation having a peak power level of less than 5Wcm^{-2} . Advantageously, the peak power level is between about 1Wcm^{-2} and 5Wcm^{-2} . The peak power level
20 may be between about 1Wcm^{-2} and 3Wcm^{-2} .

The apparatus may include cooling means for controlling the temperature of the illuminating device. The control unit is preferably arranged to control operation of any such cooling means. The control unit may conveniently comprise a suitably
25 pre-programmed microprocessor.

In accordance with the present invention there is also provided a use of said apparatus including illuminating a surface within a distance of no more than 1000mm from the illuminating device with radiation of an energy such that an area of at least
30 12mm^2 receives energy from the illuminating device during a period of at least 100ms of at least 0.01Jcm^{-2} , the radiation including radiation having a wavelength of between 350 and 700nm

(preferably including radiation having a wavelength of between 570 nm and 600 nm and/or of between 390nm and 420nm), the energy received from the illuminating device at said area in any given period of 10 μ s being less than 0.5 Jcm⁻², and the energy received from the illuminating device in any given period of 100ms being less than 5 Jcm⁻². Said use is advantageously, but not necessarily, performed to treat a skin condition on the skin of a human. The use of the apparatus may for example be in the form of performing a method of improving the cosmetic appearance of the skin and/or a method of cosmetic treatment of a skin condition. The use of the apparatus may for example be in the form of testing and/or demonstrating the apparatus on a surface that is, for example, not in the form of the skin of a living animal or human.

The apparatus of the invention is advantageously so arranged that the apparatus may be used to treat the skin of a patient without the need to pre-cool the skin before treatment.

According to another aspect of the invention there is provided a method for the treatment of a skin condition

comprising the steps of

providing an illuminating device, and

operating the illuminating device to direct light radiation on to an area of skin affected by the skin condition, wherein

during a single treatment, lasting at least 100ms, said area receives light energy from the illuminating device of at least 0.01Jcm⁻²,

the light energy so delivered in any given period of 10 μ s is less than 0.5 Jcm⁻²,

the light energy so delivered in any given period of 100ms is less than 5 Jcm⁻², and

the light energy so delivered causes a photochemical reaction within the affected skin which at least partially disables or destroys agents causing the skin condition.

There is also provided according to another aspect of the invention a method of improving the cosmetic appearance of a region of the skin, for example of a mammal, comprising the steps of

providing an illuminating device, and
operating the illuminating device to direct light radiation on to the region of skin, wherein
during a period of at least 100ms, said region receives light energy from the illuminating device of at least 0.01Jcm^{-2} ,
the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5Jcm^{-2} , and
the light energy so delivered in any given period of 100ms is less than 5Jcm^{-2} .

There is also provided a method for the cosmetic treatment of Acne Vulgaris comprising the steps of

providing an illuminating device, and
operating the illuminating device to direct light radiation on to an area of skin affected by Acne Vulgaris, wherein
during a single treatment, lasting at least 100ms, said area receives light energy from the illuminating device of at least 0.01Jcm^{-2} ,

the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5Jcm^{-2} ,

the light energy so delivered in any given period of 100ms is less than 5Jcm^{-2} , and

the light energy so delivered causes a photochemical reaction within the affected skin which at least partially

disables or destroys bacteria contributing to the symptoms of Acne Vulgaris.

The light energy so delivered advantageously causes a photochemical reaction within the skin. The method may be non-
5 therapeutic. In particular, the illuminating device may be operated in such a way as to cause no therapeutic effect on the region of skin. Conducting the method may however result in the cosmetic appearance of the affected area of skin being improved.

By providing direct light radiation for a longer period of
10 time than prior art methods, similar photon or energy densities can be delivered but at much lower power densities or energy flux densities, thereby reducing the likelihood of any adverse reactions of the skin to the radiation, for example, causing photo-mechanical effects (explosive expansion of the tissue) or
15 photo-thermal effects (rapid heating of the tissue). In addition, providing radiation at lower power means the radiation is less likely to induce erythema (redness of the skin). Advantageously, the method of the invention is performed without any active pre-cooling of the skin immediately before treatment. Some prior art
20 methods utilising higher light intensities than in the present invention cause the target area to be heated so quickly that heat cannot be effectively dissipated by means of the vascular system, such methods thus requiring cooling of the skin before treatment to prevent undesirable effects associated with the over-heating
25 of the skin.

Preferably, during said period of at least 100ms, said region receives light energy from the illuminating device of less than 10kJcm^{-2} , and more preferably less than 1kJcm^{-2} . Preferably, during said period of at least 100ms, no more than 100Jcm^{-2} of
30 light energy is delivered over any given period of 1 minute. The method may be so performed that during said period of at least 100ms, no more than 100Jcm^{-2} of light energy is delivered over

any given period of 10 minutes. The light energy so delivered in any given period of 1ms is preferably less than 1Jcm^{-2} . The light energy so delivered in any given period of 10ms is preferably less than 1Jcm^{-2} . The light energy so delivered in
5 any given period of $500\mu\text{s}$ is preferably less than 1Jcm^{-2} . Said period is preferably less than 10 hours.

The light energy so delivered in any given period of $10\mu\text{s}$ is preferably less than 50mJcm^{-2} , more preferably is less than 10mJcm^{-2} , and yet more preferably is less than 5mJcm^{-2} . The light
10 energy so delivered in any given period of $10\mu\text{s}$ may be less than 1mJcm^{-2} .

The lower power requirements of the present invention compared to prior art methods means that LEDs (Light Emitting Diodes) can be used rather than lasers. At low powers, these
15 tend to be cheaper and less complicated than equivalent laser systems. Also the use of laser devices is in many countries subject to strict regulations. The illuminating device thus advantageously includes a plurality of LEDs, for example, including a plurality of LEDs grouped together to form an array.
20 A single LED may be used. For example, the LEDs may form a 1 dimensional line array or a 2 dimensional array suitable for illumination of larger areas such as the face or back. Advantageously, the LEDs could be grouped to form a face mask under which a user (i.e. a person whose skin is affected by a
25 skin condition) could be positioned. Using such a face mask system enables a substantially uniform dose of radiation to be applied to the whole face within a short amount of time, for example in a period as short as 30 seconds. In contrast, it can take up to 30 minutes for an operator to treat a whole face using
30 the single spot applicator system. In both cases, the skin would

receive a similar dose of light radiation to induce a similar photochemical response.

The method may be utilised in a method of therapeutic treatment on the human body. The method may alternatively be
5 non-therapeutic, in that the method does not treat a skin disease; rather, the method treats a skin condition. The method may be in the form of a method of cosmetic treatment.

The method is preferably for the cosmetic treatment of Acne Vulgaris. The method may be in the form of a method for the
10 cosmetic treatment of Rosacea.

The "skin" referred to may be the skin of a mammalian animal, preferably human. The method is advantageously non-surgical. For example, the illuminating device is preferably arranged and configured so as to be unable to be operated at sufficiently high
15 power to be considered a surgical device necessitating a skilled operator, such as a surgeon. Such features provide a key advantage in that the illuminating device may thus be arranged to be intrinsically more safe and less complex to operate and manufacture than the pulsed dye laser of apparatuses of the prior
20 art.

Performance of the method may cause a photo-chemical reaction in the skin that disables or destroys, wholly or partially, the bacteria *Propionibacterium acnes*, which, as described above, is one of the causes of Acne Vulgaris.
25 *Propionibacterium acnes* is anaerobic and is harmed by the presence of oxygen. The photo-chemical reaction may be such that the symptoms of acne are, at least temporarily, reduced without permanently destroying the agents, for example the bacteria, that contribute to the symptoms of a skin condition.

30 The photo-chemical reaction may take place in a substance as a result of that substance absorbing radiation within a range of particular wavelengths (the reaction being significantly slower

or non-existent outside the range). Preferably the wavelength of radiation used produces a photo-chemical reaction in a substance (a chromophore, for example) of, on or in the skin that results in the production of free radicals (for example in the form of oxygen singlets) which thereafter may destroy the bacterium. The chromophore targeted is preferably Porphyrin. Porphyrin is a naturally occurring substance produced by the bacteria *Propionibacterium acnes*. Porphyrin produces singlet oxygen when excited by light of a wavelength of around 585nm (yellow light) and also when excited by light of a wavelength of around 405nm (violet/near ultra-violet light). Light at other wavelengths is also able to stimulate free-radical production.

Thus by exciting Porphyrin in the manner outlined above it is possible to disable or destroy the bacterium responsible for *Acne Vulgaris* in a pain-free, non-invasive and efficient manner. The method according to the present invention provides a means of destroying, at least partially, the bacteria that contributes to a skin condition but without needing to use high power lasers, which as mentioned above have various disadvantages.

The duration of the treatment or the length of the period during which light radiation is provided by the illuminating device may, for example, be between 100ms and 30 minutes, is preferably between 200ms and 10 seconds, is more preferably between 200ms and 3 seconds and is yet more preferably between 300ms and 2 seconds. The duration or period may alternatively or additionally be greater than 500ms. The delivery of light radiation may continuous during a single treatment or during said period. Alternatively, the delivery of light radiation may be pulsed during a single treatment or during said period.

The duration of the light radiation is preferably substantially greater than the thermal relaxation time of the microvascular system near the area of skin affected by the skin

condition. Thus, the photo-thermal response taught in GB2368020 is not significant in the proposed method due to the relatively low dose of light radiation energy supplied within the hundreds of micro-seconds timescale (of the same order of time as that of
5 the microvascular thermal relaxation timescale).

The energy density of the illuminating radiation delivered may, for example, be between 0.01 and 100 Jcm⁻², is preferably between 0.1 and 10 Jcm⁻², is more preferably between 0.5 and 3 Jcm⁻² and is even more preferably between 1 and 3 Jcm⁻². The
10 energy density may be less than 2 Jcm⁻². Lower energy densities are preferable at longer durations.

The dominant wavelength of the illuminating radiation is preferably pre-determined. The radiation may, for example, include radiation having a wavelength of between 350nm and 1500nm,
15 or more preferably between 350nm and 1000nm. The wavelength is preferably between 350nm and 700nm, more preferably between 570nm and 600nm and is even more preferably between 580nm and 590nm. The illuminating radiation may include radiation substantially concentrated around the wavelength of yellow light (585nm). The
20 radiation may include radiation having a wavelength of between 350nm and 450nm, or more preferably between 390nm and 420nm. The illuminating radiation may include radiation substantially concentrated around the wavelength of violet/near ultra-violet light (405nm). In accordance with the invention, especially
25 insofar as the treatment for Acne Vulgaris is concerned, the radiation may be chosen to correspond to a photosensitizer such as for example porphyrin in skin tissue. The wavelength of the light radiation may be chosen to correspond with a wavelength suitable for targeting the porphyrin in the skin layers at a
30 depth suitable to ensure that singlet oxygen is released which affects the proprionibacterium Acnes without significantly affecting other tissues.

It is especially advantageous to use radiation at one or more wavelengths that correspond to one or more of the peaks of the porphyrin absorption curve.

5 The illuminating radiation may be provided to an area of the affected skin of between 12 and 200mm², for example, to a spot size of diameter 4-16mm. The area may be less than 100mm². A greater area may be treated however. For example an area of up to 0.1m² or even up to 0.5m² might be treated simultaneously.

10 Preferably the illuminating radiation delivered has a peak optical power level of less than 100Wcm⁻² and more preferably less than 10W cm⁻². The illuminating radiation preferably provides a peak optical output power level of between 1 and 5Wcm⁻².

15 The light energy so delivered by the illuminating device may cause a photochemical reaction within the affected skin thereby stimulating the production of free-radicals, which react with, and at least partially disable or destroy, agents causing the skin condition.

20 A low power spot or line treatment may be used to "top up" the higher dose treatment described above. The top up treatment may for example be provided at lower powers than the higher dose treatment and over longer periods of time (for example, overnight). Such a low power treatment might be particularly well suited to use of the illuminating device in the home.

25 The method is preferably performed such that the distance between the illuminating device and the surface onto which the radiation is delivered is less than 1000mm, and is preferably less than 100mm. The distance of separation may be less than 50mm. The illuminating device and the surface may be directly adjacent to each other and may for example touch when radiation is being delivered.

30

Above, mention is made of light energy causing a photochemical reaction within the skin. In order to cause a photochemical reaction in the skin, it is believed that the extent/amount of the photochemical reaction depends primarily on the amount of light (i.e. number of photons) received per unit area and that the power of light used has a lesser effect. According to certain embodiments of the invention, it is preferred for the light energy to be delivered over a relatively long period of time. According to certain other embodiments of the invention, it is preferred for the light energy to be delivered over a relatively short time without exceeding a given power level that might cause undesirable effects resulting from heating of the skin. Thus according to some aspects of the invention it is preferred to have as high a power output as is reasonably possible without exceeding a maximum power output, above which there would be a risk of causing such undesirable effects. It is considered especially advantageous that the present invention is able to provide an apparatus that utilises semiconductor light emitting devices (such as LEDs or laser diodes) that are able to operate at such power levels.

It will be appreciated that the method of the invention may include use of the apparatus of the invention and that the apparatus of the invention may be arranged and configured to be suitable for performing the method of the invention. Thus, features described with reference to the method of the invention may be incorporated in the apparatus of the invention. Also, features described with reference to the apparatus of the invention may be incorporated in the method of the invention.

An embodiment of the present invention will now be described by way of example with reference to the following schematic drawings of which:

Figure 1 shows an apparatus including a control unit and an illuminating device being used to treat the skin of a patient;

5 Figure 2 shows the control unit and illuminating device of the apparatus shown in Figure 1; and

Figure 3 shows in greater detail the illuminating device of the apparatus shown in Figure 1.

10 Figure 1 shows an apparatus 10 for the treatment of a skin condition such as acne by directing light radiation 12 onto the skin 11 of a human patient. The skin to be treated in this embodiment is an area of skin on the face including a spot having a diameter about 6mm. The apparatus 10, in this embodiment a hand-held battery powered unit, includes an illuminating device 1 and a control unit 9 linked thereto which controls the radiation
15 emitted by the device 1. The housing of the apparatus 10 is elongate in shape and has a proximal end via which light is emitted from the illuminating device 1. The overall length of the housing is about 15cm.

20 The apparatus 10, in use, is placed against the skin with the illuminating device 1 being positioned so as to direct radiation towards the affected area. Before operation the apparatus is programmed to set the duration of the radiation and the power of radiation. In this embodiment the apparatus is set
25 to provide a single pulse of light energy lasting 1 second that delivers 1.5 Jcm^{-2} to the 6mm diameter spot. The peak power output of the illuminating device 1 is below 5 W/cm^{-2} . The energy profile over time of the radiation delivered is such that the energy is continuously delivered during the 1 second pulse and is
30 such that during any period of $10 \mu\text{s}$ the light energy delivered is less than 0.5 Jcm^{-2} and such that during any period of 100ms the

light energy delivered in is less than 5 Jcm^{-2} . The method of this embodiment relies solely on photochemical effects that occur within the skin as is explained in further detail below. In general, it is preferable that the method of the invention is so performed that, and/or the apparatus of the invention is so arranged that in normal use, there is substantially no beneficial photo-thermal reaction caused within the skin.

The radiation received by the skin 11 causes a photochemical reaction in Porphyrin in the skin that releases singlet oxygen (a free radical), which then destroys at least some of the bacteria, which is one of the causes of the symptoms of acne. The radiation received is however well below the level at which erythema may be induced. The radiation emitted by the illuminating device includes light having an intensity that peaks at a wavelength of about 585nm and includes components of light radiation having wavelengths in the range of 570-600nm. Such wavelengths are suitable for targeting the porphyrin in the skin layers at a depth sufficient for causing the released reactive oxygen to affect the Propionibacterium acnes bacteria without significantly affecting other tissues.

The illuminating device includes a plurality of LEDs 7 arranged in a 2-D array 2 (shown schematically in Figure 2 as LEDs arranged in a close-packed formation) connected to a lens arrangement (not shown) that focuses the radiation emitted by the LEDs, so that a concentrated source of light is provided. The device 1 is therefore suitable for "spot treatment" of skin condition (i.e. treating small areas one at a time). Figure 3 shows other components of the illuminating device 1, such other components being provided to cool the LEDs.

Referring to the Fig. 3, there is shown illuminating device (generally designated 1) comprising, in sequence, an LED diode array 2, a high thermal conductivity heat spreader layer 3, a

Peltier type thermoelectric cooler 4 and a heat pipe arrangement 5 (including a distal condenser 6).

5 The heat spreader 3, thermoelectric cooler 4 and heat pipe arrangement 5 are provided to keep the operating temperature of the LEDs at a reduced level and therefore operating most efficiently. It is well-known that the efficiency of an LED increases with reduced operating temperature and in the case of LEDs operating at wavelengths between 550nm and 650nm this dependence on temperature is very high.

10 Heat flowing from the LED diode array 2 is spread over a larger area by the high conductivity spreader layer 3. This layer is typically only a few millimetres thick and provides rapid and highly efficient heat transfer away from the diode array 2. Heat then flows into the cold end of the thermoelectric
15 Peltier cooler 4. The hot end of the thermoelectric Peltier cooler layer 4 is in heat transfer coupling with the heat pipe 5. The high thermal conductivity layer 3 includes a diamond material, which is laid down by means of a plasma/chemical vapour deposition method.

20 The Peltier cooler 4 includes a separate control means including associated drive circuitry which accurately controls, during use, the heat transfer away from the LED diode array 2 via the high thermal conductivity spreader layer 3. Accurate control of the driven Peltier thermoelectric cooler 4 (in combination
25 with the provision of the high thermal conductivity heat spreader layer 3 and the downstream heat pipe cooling arrangement 5) provides for extremely efficient thermal management of the apparatus, and in particular the diode array 2, which ensures consistency of the light output.

30 The heat pipe arrangement 5 includes a wick to direct fluid coolant (contained in the heat pipe arrangement 5) away from the "hot zone" via capillary action, gravity or diffusion. The

arrangement includes a fluid return system to return cooled fluid from the "cold zone" at the distal end of the apparatus, which is provided with a condenser 6. The condenser 6 is itself cooled by air cooling.

5 The treatment of Acne using this method has been / will be trialled on patients suffering from facial acne. The illuminating device used in these trials was in the form of a small spot illuminating device (as described above). During the trials, the radiation emitted during a single dose was about
10 1.5J/cm⁻² for a 6mm spot size. Trials are also planned with the use of the illuminating device similar to that described above but being in the form of a larger 2-D array of such devices. Such an array of devices would for example be suitable for illumination and treatment of larger areas such as the face or
15 back. The results of the initial trials appear to demonstrate a beneficial effect on the skin conditions treated.

It will be appreciated that various modifications may be made to the above-described embodiments of the invention without departing from the spirit of the invention. For example, the
20 illuminating device used may be in the form of any illuminating device able to produce controlled doses of radiation at appropriate energy levels and wavelengths, without exceeding certain power levels. For example, the illuminating device may be in the form of a line of a plurality of the illuminating
25 devices described above (a "line treatment") or could be in the form of the 2-D array of devices as proposed for use in the trials (a "wide area treatment"). There may also be provided a lower fluence device for spot treatment or for line treatment that can be used to "top-up" the higher dosage spot treatment
30 described above. Such a low fluence device would be particularly suitable for home-use.

In the embodiment described above, the wavelength of radiation used is in the range 570-600nm. However, other embodiments are envisaged that target other peaks in the porphyrin absorption within the skin tissue. Thus, for example
5 light radiation having wavelengths in the violet/near ultra-violet light, blue, green and red wavelength bands could also be used, either individually, or in various combinations. The light could be emitted from a single apparatus (possibly from a single illuminating device) or by separate apparatuses. The control
10 unit would of course control the relative levels of light for the different colours to deliver differing amounts of reactive light at different depths in the skin - thereby tailoring the proposed treatment dependent on the depth of infection by the *Propionibacterium acnes* bacteria.

CLAIMS

1. An apparatus for the treatment of a skin condition comprising

5 an illuminating device, and

a control unit for controlling the operation of the illuminating device, wherein

the illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and
10 wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by a skin condition, which reaction would result in agents causing the skin condition being at least partially disabled or destroyed, and

the control unit and illuminating device are so arranged and
15 configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:

the light energy received at said area during a period of at
20 least 100ms is at least 0.01Jcm^{-2} ,

the light energy received at said area in any given period of $10\mu\text{s}$ is less than 0.5Jcm^{-2} , and

the light energy so delivered in any given period of 100ms is less than 5Jcm^{-2} , whereby

25 the apparatus may be used to treat the skin condition.

2. An apparatus according to claim 1, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the
30 single dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during

the single dose being greater than 0.1 Jcm^{-2} and being equal to $T_1 \times P_1$, where T_1 = the length in time of the single dose and P_1 has the units of optical power density (power per unit area) and satisfies $0.2 \text{ Wcm}^{-2} < P_1 < 20 \text{ Wcm}^{-2}$.

- 5 3. An apparatus according to claim 1, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10
10 seconds and the energy of the light radiation delivered during the single dose being equal to $T_2 \times P_2$, where T_2 = the length in time of the single dose and P_2 has the units of optical power density (power per unit area) and satisfies $0.01 \text{ Wcm}^{-2} < P_2 < 1 \text{ Wcm}^{-2}$.
- 15 4. An apparatus according to claim 2 or claim 3, wherein the apparatus is so configured and arranged that, during a single dose of light radiation, an area of skin of between 12 and 200 mm^2 is treated.
- 20 5. An apparatus according to claim 1, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10 hours, light radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than 0.1 Jcm^{-2} and being equal to
25 $T_3 \times P_3$, where T_3 = the length in time of the single treatment and P_3 has the units of optical power density (power per unit area) and satisfies $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$.
- 30 6. An apparatus according to claim 5, wherein the apparatus is so configured and arranged that, during a single treatment, an area of skin of between 0.003 and 0.5 m^2 is treated.

7. An apparatus according to any preceding claim, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between 570nm and 600nm.

8. An apparatus according to any preceding claim, wherein the
5 illuminating device is arranged to provide light radiation including radiation having a wavelength between 390nm and 420nm.

9. An apparatus according to any preceding claim, wherein the illuminating device comprises one or more light emitting semiconductor devices.

10 10. An apparatus according to claim 9, wherein the or each semiconductor device is in the form of a diode.

11. Use of an apparatus according to any preceding claim, including illuminating a surface within a distance of no more than 1000mm from the illuminating device with radiation of an
15 energy such that an area of at least 12mm^2 receives energy from the illuminating device during a period of at least 100ms of at least 0.01Jcm^{-2} , the radiation including radiation having a wavelength of between 570 nm and 600 nm, the energy received from the illuminating device at said area in any given period of $10\mu\text{s}$
20 being less than 0.5Jcm^{-2} , and the energy received from the illuminating device in any given period of 100ms being less than 5Jcm^{-2} .

12. A method of improving the cosmetic appearance of a region of skin by means of conducting the non-therapeutic steps of

25 providing an illuminating device, and
operating the illuminating device to direct light radiation on to the region of skin, wherein

during a period of at least 100ms, said region receives light energy from the illuminating device of at least 0.01Jcm^{-2} ,

30 the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5Jcm^{-2} , and

the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} .

13. A method according to claim 12, wherein the light energy so delivered causes photochemical reaction within an area of skin affected by a skin condition, the reaction at least partially disabling or destroying bacteria contributing to the symptoms of the skin condition.

14. A method for the cosmetic treatment of Acne Vulgaris comprising the steps of

10 providing an illuminating device, and
operating the illuminating device to direct light radiation on to an area of skin affected by Acne Vulgaris, wherein during a single treatment, lasting at least 100ms, said area receives light energy from the illuminating device of at least
15 0.01 Jcm^{-2} ,

the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} ,

the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} , and

20 the light energy so delivered causes a photochemical reaction within the affected skin which at least partially disables or destroys bacteria contributing to the symptoms of Acne Vulgaris.

15. A method according to claim 13 or claim 14, wherein the photochemical reaction stimulates the production of free-radicals, which then react with, and at least partially disable or destroy, agents causing the skin condition.

16. An apparatus according to any of claims 1 to 11, wherein the apparatus is arranged and configured so as to be suitable for use
30 in the method as claimed in any of claims 12 to 15.

- 27 -

17. An apparatus substantially as herein described with reference to any of the accompanying drawings.

Amendments to the claims have been filed as follows

1. An apparatus for the cosmetic treatment of a skin condition comprising

an illuminating device, and

a control unit for controlling the operation of the illuminating device, wherein

the illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by the skin condition, which reaction would result in agents causing the skin condition being at least partially disabled or destroyed and the illuminating device is so arranged and configured so that, in use, substantially no beneficial photo-thermal reaction occurs within the said area of skin, and

the control unit and illuminating device are so arranged and configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:

the light energy received at said area during a period of at least 100ms is at least 0.01 Jcm^{-2} ,

the light energy received at said area in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and

the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} , whereby

the apparatus may be used to treat the skin condition.

- 29 -

2. An apparatus as claimed in claim 1, wherein said skin condition is Acne Vulgaris.

3. An apparatus according to claim 1 or claim 2, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during the single dose being greater than 0.1 Jcm^{-2} and being equal to $T_1 \times P_1$, where T_1 = the length in time of the single dose and P_1 has the units of optical power density (power per unit area) and satisfies $0.2 \text{ Wcm}^{-2} < P_1 < 20 \text{ Wcm}^{-2}$.

4. An apparatus according to claim 1 or claim 2, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during the single dose being equal to $T_2 \times P_2$, where T_2 = the length in time of the single dose and P_2 has the units of optical power density (power per unit area) and satisfies $0.01 \text{ Wcm}^{-2} < P_2 < 1 \text{ Wcm}^{-2}$.

5. An apparatus according to claim 3 or claim 4, wherein the apparatus is so configured and arranged that, during a single dose of light radiation, an area of skin of between 12 and 200 mm^2 is treated.

6. An apparatus according to claim 1 or claim 2, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10 hours, light radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than 0.1 Jcm^{-2} and being equal to $T_3 \times P_3$, where T_3 = the length in time of the single treatment and P_3 has the units of optical power density (power per unit area) and satisfies $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$.
7. An apparatus according to claim 6, wherein the apparatus is so configured and arranged that, during a single treatment, an area of skin of between 0.003 and 0.5 m^2 is treated.
8. An apparatus according to any preceding claim, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between 570 nm and 600 nm .
9. An apparatus according to any preceding claim, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between 390 nm and 420 nm .
10. An apparatus according to any preceding claim, wherein the illuminating device comprises one or more light emitting semiconductor devices.
11. An apparatus according to claim 10, wherein the or each semiconductor device is in the form of a diode.

12. Use of an apparatus according to any preceding claim, including illuminating a surface within a distance of no more than 1000mm from the illuminating device with radiation of an energy such that an area of at least 12mm^2 receives energy from the illuminating device during a period of at least 100ms of at least 0.01Jcm^{-2} , the radiation including radiation having a wavelength of between 570 nm and 600 nm, the energy received from the illuminating device at said area in any given period of $10\mu\text{s}$ being less than 0.5Jcm^{-2} , and the energy received from the illuminating device in any given period of 100ms being less than 5Jcm^{-2} .

13. A method of improving the cosmetic appearance of a region of skin by means of conducting the non-therapeutic steps of

providing an illuminating device, and
operating the illuminating device to direct light radiation on to the region of skin, wherein

during a period of at least 100ms, said region receives light energy from the illuminating device of at least 0.01Jcm^{-2} ,

the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5Jcm^{-2} , and

the light energy so delivered in any given period of 100ms is less than 5Jcm^{-2} , wherein the light energy so delivered causes photochemical reaction within an area of skin affected by a skin condition, the reaction at least partially disabling or destroying bacteria contributing to the symptoms of the skin condition, and wherein the light

- 32 -

energy so delivered causes substantially no beneficial photo-thermal reaction to occur within the said area of skin.

14. A method as claimed in claim 13, wherein said light radiation is directed on to an area of skin affected by Acne Vulgaris and

the light energy so delivered causes a photochemical reaction within the affected skin which at least partially disables or destroys bacteria contributing to the symptoms of Acne Vulgaris.

15. A method according to claim 13 or claim 14, wherein the photochemical reaction stimulates the production of free-radicals, which then react with, and at least partially disable or destroy, agents causing the skin condition.

16. An apparatus according to any of claims 1 to 12, wherein the apparatus is arranged and configured so as to be suitable for use in the method as claimed in any of claims 13 to 15.

17. An apparatus substantially as herein described with reference to any of the accompanying drawings.



INVESTOR IN PEOPLE

Application No: GB 0301740.7
Claims searched: 1 to 17

Examiner: Matthew Parker
Date of search: 3 July 2003

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1, 3-7, 9-16	EP 0726083 A2 (ESC), see page 6, lines 18 to 21
X	1-6, 8-10 12-16	US 2002/0161418 (WILKENS), see page 2, paragraph [0020]
A		GB 2368020 A (ICN)

Categories:

X Document indicating lack of novelty or inventive step	A Document indicating technological background and/or state of the art.
Y Document indicating lack of inventive step if combined with one or more other documents of same category.	P Document published on or after the declared priority date but before the filing date of this invention.
& Member of the same patent family	E Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^v:

A5R

Worldwide search of patent documents classified in the following areas of the IPC⁷:

A61N

The following online and other databases have been used in the preparation of this search report:

Online: EPODOC, JAPIO, WPI